AAMI

Advancing Safety in Health Technology

AAMI Consensus Report

Basic Introduction to the IEC 60601 Series

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Basic Introduction to the IEC 60601 Series

Approved December 2019 by
AAMI

Abstract This document provides information regarding concepts and principles that underlie the IEC 60601 series of standards. (The IEC 60601 series is defined in the Introduction.) This document is intended to clarify and to point out the importance of the series as well as to provide guidance to understanding and to implementing the series.

Key Words electromedical equipment, medical electrical equipment, medical electrical systems, basic safety, essential performance, risk management

AAMI Consensus Report

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- When existing standards or other documents require additional context/clarification

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Rd, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

This AAMI Consensus Report (CR) was developed by an AAMI Task Group specially formed for this project. The members of the task group are listed below.

This CR was reviewed by the **AAMI Electrical Safety Committee** and the **AAMI Application of risk management to medical devices Working Group** and approved by the **AAMI Electrical Safety Committee.**

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This consensus-driven document was proposed as new work and developed initially by employees of the U.S. Food and Drug Administration (FDA). A task group composed of representatives of manufacturers, testing laboratories, and accreditation bodies met with representatives from the FDA and finalized the document.

The Association for the Advancement of Medical Instrumentation (AAMI) administers the Secretariat for IEC Subcommittee (SC) 62A, "Common aspects of electrical equipment used in medical practice," and Subcommittee (SC) 62D, "Electromedical equipment."

AAMI also supports the U.S. TAG (technical advisory group) for the two SCs as well as Technical Committee (TC) 62, "Electrical equipment in medical practice."

As part of the consensus-driven process of the AAMI standards program, this document was circulated for comments to the AAMI Electrical Safety Committee and the AAMI Application of Risk Management to Medical Devices Working Group. This document was also balloted for approval by the AAMI Electrical Safety Committee, the primary group that adopts the IEC 60601-1 standard.

It is hoped that this document will be useful for users of the IEC 60601 series.

Suggestions for improving this document are invited. Comments and suggestions should be forwarded to the AAMI Standards Program, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Introduction

This document explores how medical device manufacturers and their stakeholders–including FDA and other regulators–can best make use of the IEC 60601 series of safety standards to assure the safety of users/operators and patients. This document takes a holistic and pragmatic view of the subject, starting with an examination of the concepts and rationale underlying the development of the standards that comprise the 60601 series.

The IEC 60601 series constitutes a massive and complex body of work. The original standard, IEC 601, dates to 1977. This standard has been updated and now is in its 3rd edition. This edition has been adopted as an American National Standard, ANSI/AAMI ES60601-1, which runs over 400 pages. Eight *collateral* standards add requirements having general (horizontal) applicability to all medical electrical equipment (MEE) or medical electrical systems (MES) within the scope, covering such topics as alarm safety, radiation protection, and the use of medical equipment in the home and emergency medical service environments. The vertical or device-specific *particular* standards provide safety and performance requirements for specific types of medical electrical equipment or medical electrical systems. The general standard normatively references close to 50 ISO and IEC standards, and informatively references an additional 70-plus standards[1]. In a subsequent section, we will go into greater detail about the structure and organization of the series.

IEC Technical Committee (TC) 62, *Electrical equipment in medical practice*, is responsible for the care and maintenance of the IEC 60601 series. Within TC 62, there are 4 subcommittees, with given responsibilities as outlined below. The subcommittees head up 80 or more working groups, maintenance teams, joint working groups, and advisory boards working on different aspects of the committee's program.

- SC 62A, "Common aspects of electrical equipment used in medical practice" (responsible for general and most of the collateral standards along with related documents for horizontal issues)
- SC 62B, "Diagnostic imaging equipment" (responsible for 60601-2-x and particular standards and related documents in the subject matter of imaging equipment)
- SC 62C, "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" (responsible for particular standards and related documents in the subject matter)
- SC 62D, "Electromedical equipment" (responsible for particular standards that have not been covered by the other three SCs)

Given the size and complexity of this body of work, it is a challenge to gain more than a superficial understanding of what the 60601 series of standards encompasses, let alone why it matters. Therefore, a key objective of this document is to provide stakeholders with sufficient information about the 60601 series to grasp its significance and value. At the same time, it is important to know what the 60601 series excludes, so that stakeholders can understand the role it plays in the broader context of assuring the safety and effectiveness of MEE/MESs.

[1] Normatively referenced standards are the basis for the associated requirements in 60601-1. Informative references are for information only.

IEC 60601 series

IEC 60601 series: A set of publications of IEC or ISO based on, and following the rules specified in, IEC 60601-1.

Note 1 to entry: For historical reasons, some PARTICULAR STANDARDS based on IEC 60601-1 are numbered differently, such as the following:

- IEC 80601-2-59, *Medical electrical equipment—Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*
- ISO 80601-2-12, *Particular requirements for basic safety and essential performance of critical care ventilators*
- ISO 11197, *Medical supply units*

Note 2 to entry: IEC TR 60513:1994 clause 19.4 specifies for the edition 3 of the IEC 60601 series:

"The relationship between the third edition of IEC 60601-1 and its collateral and particular standards should follow the current approach. The series should consist of:

a) a general standard, IEC 60601-1, containing safety and essential performance requirements that are common to all medical electrical equipment;
b) a series of collateral standards, IEC 60601-1-xx, containing additional safety and essential performance requirements that are common to a range of medical electrical equipment;
c) a series of particular standards, IEC 60601-2-xx, containing additional safety and essential performance requirements for particular types of medical electrical equipment.

"Experience has shown that, because of the extensive nature of the document, up to a decade is required to complete a full revision of IEC 60601-1 as a single document. It was therefore appropriate to publish the third edition as a series of separate sections, all referred to in a reduced general (or parent) publication, as shown in Table 3 and Figure 2 of IEC TR 60513:1994."

Basic Introduction to the IEC 60601 Series

1 Overview of the 60601 Series

1.1 Scope and structure

The scope of IEC 60601 has evolved over the years and now includes all medical electrical equipment and systems[2] that are in contact with or used in proximity to patients in clinical, preclinical, and non-clinical environments. Implantable medical devices are explicitly excluded from the scope, as are medical devices used outside the patient environment, such as in vitro diagnostic (IVD) medical devices used in a laboratory environment.

The focus of IEC 60601 is on evaluating the adequacy of a MEE/MES design from the perspective of safety prior to its placement on the market. The requirements of the standard address many aspects of device construction and design features intended to mitigate recognized risks. Production and post-production activities are considered only in a few instances where these activities might foreseeably compromise the effectiveness of a risk mitigation.[3]

There is a widespread misperception that the 60601 series is focused on electrical safety, when, in fact, its scope is the overall safety of medical equipment. Electrical safety is only a part of the safety aspects addressed by the IEC 60601 series.

The structure of the 60601 series consists of the general standard (IEC 60601-1) and three branches, as shown in Figure 1. The three branches - collaterals, particulars and technical reports - are explained in the following sections.

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[2] "MEDICAL ELECTRICAL EQUIPMENT

ME EQUIPMENT

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used: 1) in the diagnosis, treatment, or monitoring of a PATIENT; or 2) for compensation or alleviation of disease, injury or disability" (ANSI/AAMI ES60601-1:2015 (2012), subclause 3.63)

MEDICAL ELECTRICAL SYSTEM

ME SYSTEM

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be interconnected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET" (ANSI/AAMI ES60601-1:2015 (2012), subclause 3.64)

[3] For example, see subclauses 4.9, 8.6.5, and 9.8.1 of AAMI ES60601-1:2005/(R)2012 and A1:2012.